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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/044,031	01/11/2002	Stephen F. Badylak	3220-69262	9094
23643	7590	06/03/2004		
BARNES & THORNBURG 11 SOUTH MERIDIAN INDIANAPOLIS, IN 46204			EXAMINER PREBILIC, PAUL B	
			ART UNIT 3738	PAPER NUMBER

DATE MAILED: 06/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/044,031

Applicant(s)

BADYLAK ET AL.

Examiner

Paul B. Prebilic

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 18 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 and 16-20 is/are rejected.
- 7) ☒ Claim(s) 14 and 15 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 11-08-02.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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### ***Specification***

The disclosure is objected to because of the following informalities:

On page 1, the continuing data needs to be updated with the current status of the parent application, which is now abandoned.

Appropriate correction is required.

### ***Information Disclosure Statement***

The information disclosure statement filed November 18, 2002 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has only been considered to the extent indicated by the initialed references. In particular, Applicants stated that all the cited references were made of record in the grandparent application 08/916,490. However, upon review of the patent, it became evident that only some of the documents cited on the November 18, 2002 PTO-1449 were actually of record in that application. For that reason, the Examiner considered only those patents and document that were cited therein. The Examiner struck references that were not provided or not of record in the grandparent application. Applicants are respectfully requested to provide copies of the missing documents if they wish that they be considered before a next Office action is mailed.

### ***Double Patenting***

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or

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discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-7 and 11-13 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-3, 5-7, 19, 22, 26, and 29 of prior U.S. Patent No. 6,206,931. This is a double patenting rejection.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 8, 10, and 16-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 10 and 34-38 of U.S. Patent No. 6,206,931. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claim sets are so similar to each other that they can be read on each other either one way or the other. For this reason, the claims are considered to be obvious in view of each other.

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Claim 9 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 20 of U.S. Patent No. 6,206,931 in view of Kemp (US 5,460,962). Claim 9 is met by the features set forth in patented claim 20 except for the oxidizing agent used to treat the tissue. However, Kemp teaches that it was known to treat like tissues with the oxidizing agent peracetic acid in order to sterilize the same; see the abstract. Therefore, it is the Examiner's position that it would have been prima facie obvious to treat the tissue of claim 9 with the oxidizing agent peracetic acid as taught by Kemp in order to sterilize the tissue as taught by Kemp.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(f) he did not himself invent the subject matter sought to be patented.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7 and 11-13 are rejected under 35 U.S.C. 102(f) as being anticipated by Cook et al (US 6,206,931). Cook et al anticipates the claim language fully; see claims 1-3, 5-7 10, 22, 26, and 29 thereof, which fully discloses the invention thereof.

Claims 8, 10, and 16-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cook et al (US 6,206,931) alone. Cook discloses substantially all the claimed features except for the cleaning step (claims 8 and 10) or the disinfecting step (claim 34 of the patent). However, since the process steps would not result in a clearly different structure from that set forth in Cook, it is the Examiner's position that the claimed invention is clearly obvious in view thereof. Furthermore, it would have been clearly obvious to clean or disinfect either the claimed device or the patented device in order to make it more suitable for implantation and in order to reduce the possibility of introducing bacteria or other contaminants into the implant site.

Claims 8, 10, and 16-20 are rejected under 35 U.S.C. 103(a) as being obvious over Cook et al (US 6,206,931).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer

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in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(I)(1) and § 706.02(I)(2).

Claims 16-20 are rejected under 35 U.S.C. 102(b) as anticipated by Kemp (US 5,460,962) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kemp (US 5,460,962) alone. Kemp discloses a sterilize tissue matrix which can be made of submucosa tissue by treating the tissue with a peracetic acid; see the abstract, column 2, line 39 to column 3, line 56 and EXAMPLE 3. Since the tissue of Kemp is the same as Applicants claimed invention and has been treated in the same way, the Examiner asserts that it necessarily has the claimed endotoxin level, tela submucosa and residual contaminants as claimed.

Alternatively, since the exact same process steps are not disclosed by Kemp as those disclosed by Applicants, it may be that only a substantially identical device is disclosed thereby. However, since the difference between Kemp and the claimed device are at most nominal, it is the Examiner's position that the claimed invention is at least obvious in view of Kemp alone; see MPEP 2113, which is incorporated herein by reference thereto.

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***Allowable Subject Matter***

Claims 14 and 15 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Prebilic whose telephone number is (703) 308-2905. The examiner can normally be reached on Monday-Thursday from 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for this Technology Center is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 3700 receptionist whose telephone number is (703) 308-0858.



Paul Prebilic  
Primary Examiner  
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